K063786

510(k) SUMMARY

Endoscopic Insufflation Unit model XECR-2

2006/10/**

1 General Information

- Applicant:
  OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent:
  Laura Storms-Tyler
  Executive Director
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5688
  FAX: 484-896-7128
  Email:Laura.storms-tyler@olympus.com
  Establishment Registration No: 2429304

- Manufacturer:
  Shirakawa Olympus Co., Ltd.
  3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
  Nishishirakawa-gun, Fukushima, JAPAN 961-8061
  Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: Endoscopic Insufflation Unit model XECR-2
- Common Name: Endoscopic Insufflator
- Regulation Number: 21 CFR No. 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: FCX and KOG

K063786

3 Predicate Device Information

Device Name	Olympus-Keymed Endoscopic CO_2 Regulator, Model ECR	E-Z-EM Endoscopic CO_2 Regulator
Common Name	Endoscopic Insufflator	Endoscopic Insufflator
Manufacturer	KeyMed, Ltd.	E-Z-EM, Inc.
510(k) No.	K881004	K053008

4 Device Description

The Endoscopic Insufflation Unit model XECR-2 is used to distend the gastrointestinal tract to optimize endoscopic observation utilizing carbon dioxide gas. The XECR-2 can be connected to both a CO2 cylinder and the medical facilities gas pipeline facility.

5 Indications for Use

This instrument has been designed to be used with Olympus gastrointestinal endoscopes and other ancillary equipment for CO2 gas and water feeding.

6 Comparison of Technological Characteristics

The Endoscopic Insufflation Unit model XECR-2 is basically identical to the predicate devices in intended use, and similar in specifications except for the addition of new functions such as a timer. The clinical literature provided in this submission support the safety and efficacy of the subject device.

7 Conclusion

When compared to the predicate devices, the XECR-2 insufflation unit does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Laura Storms-Tyler
Executive Director
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

MAR 0 5 2007

Re: K063786
Trade/Device Name: Endoscopic Insufflation Unit model XECR-2
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX
Dated: December 19, 2006
Received: December 26, 2006

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063786

Device Name: Endoscopic Insufflation Unit model XECR-2

Indications For Use:

This instrument has been designed to be used with Olympus gastrointestinal endoscopes and other ancillary equipment for CO_2 gas and water feeding.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063786